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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,506	07/31/2001	John G. Babish	T8638.NP	2768

7590 09/27/2002
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EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/919,506

Applicant(s)
Babish et al.

Examiner
Patricia Patten

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a composition for inhibition of COX-2 activity comprising a sesquiterpene lactone and diterpene lactone or triterpene, classified in class 424, subclass 725 for example.
- II. Claims 6-9, drawn to a composition for inhibition of COX-2 activity comprising a first compound such as encelin and a second component such as betulin, classified in class 424, subclass 775 for example.
- III. Claims 11-15, drawn to a composition for inhibition of COX-2 activity comprising a first compound such as melapodin A and a second compound such as glycyrrhizic acid, classified in class 424, subclass 725 for example.
- IV. Claims 16-20, drawn to a composition for inhibiting COX-2 comprising parthenolide and a compound such as ursolic acid, classified in class 424, subclass 732 for example.

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- V. Claims 21-25, drawn to a method of dietary supplementation comprising administration of a sesquiterpene lactone and diterpene lactone or triterpene, classified in class 558, subclass 12 for example.
- VI. Claims 26-28, drawn to a method of dietary supplementation comprising administration of a composition comprising constituents such as tenulin and betulin, classified in class 558, subclass 310 for example.
- VII. Claim 29, drawn to a method for dietary supplementation comprising administration of a composition comprising constituents such as melapodin A and dehydroandrographolide, classified in class 560, subclass 249 for example.
- VIII. Claim 30, drawn to a method of dietary supplementation comprising administration of a composition comprising constituents such as parthenolide and oleanolic acid, classified in class 424, subclass 728 for example.
- IX. Claim 31, drawn to a method for therapeutic treatment comprising administration of a sesquiterpene lactone and diterpene lactone or triterpene, classified in class 540, subclass 41 for example.
- X. Claim 32, drawn to a method of therapeutic treatment comprising administration of a composition comprising constituents such as leucanthin B and triperin, classified in class 514, subclass 783 for example.

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- XI. Claim 33 drawn to a method for therapeutic treatment comprising administration of a composition comprising constituents such as encelin and oleanolic acid, classified in class 552, subclass 293 for example.
- XII. Claim 34, drawn to a method for therapeutic treatment comprising administration of a composition comprising partenolide and andrographolide, classified in class 424 , subclass 774 for example.
- XIII. Claim 35, drawn to a method for therapeutic treatment comprising administration of a sesquiterpene lactone and diterpene lactone or triterpene , classified in class 540 , subclass 115 for example.
- IVX. Claim 36, drawn to a method for therapeutic treatment comprising administration of a composition comprising constituents such as psilostachyin A and deoxyandrographolide, classified in class 424, subclass 764 for example.
- XV. Claim 37, drawn to a method for therapeutic treatment comprising administration of a composition comprising parthenolide and glycyrrhetic acid, classified in class 424, subclass 773 for example.
- XIV. Claim 38, drawn to a method for therapeutic treatment comprising administration of parthenolide and ursolic acid, classified in class 424, subclass 732 for example.
- XVII. Claim 39, drawn to a method for therapeutic treatment comprising administration of a sesquiterpene lactone and diterpene lactone or triterpene, classified in class 549, subclass 263 for example.

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- XIIX. Claim 40, drawn to a method for therapeutic treatment comprising administration of a composition comprising constituents such as confertiflorin and betulinic acid, classified in class 514, subclass 175 for example.
- XIX. Claim 41, drawn to a method for therapeutic treatment comprising administration of a composition comprising constituents such as melapodin A and glycyrrhizic acid, classified in class 424, subclass 769 for example.
- XX. Claim 42, drawn to a method for therapeutic treatment comprising administration of parthenolide and andrographolide, classified in class 514, subclass 783 for example.

Inventions I-XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions may all employ different permutations of constituents which would necessarily lead to different pharmaceutical effects when administered to an individual. For example, treatment with parthenolide and glycyrrhetinic acid would produce a different effect than treatment with psilostachyin A and deoxyandrographolide. The method claims do not necessarily correspond to any of the composition claims because the methods (Groups V-XX) may be carried out with entirely different products than those claimed in Groups I-IV and are thus considered unrelated.

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The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Because these inventions are distinct for the reasons given above and the search required for each Group is not required for the others, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



CHRISTOPHER R. TATE
PRIMARY EXAMINER